K081680
p. 1 of 2

510(K) SUMMARY

JUL 10 2008

June 13, 2008

Submitted By: NuMED, Inc. , 2880 Main St., Hopkinton, NY 12965 (Ph) 315-328-4491

Contact Person: Nichelle LaFlesh

Device Name: NuMED NuCLEUS-X PTV Catheter; 21 CFR 870.1250 – Percutaneous Catheter

Predicate Devices: NuMED Z-MED-X PTV Catheter

Device Description: The NuCLEUS-X catheter is a coaxial catheter for use in for Percutaneous Transluminal Valvuloplasty (PTV) for mitral and aortic position and centered angioplasty applications. The outer body is made of polymeric tubing, and the inner tubing is comprised of a multi layer extrusion of polyamide (Vestamid PA12) that surrounds a braid of 304 LV Stainless Steel. The catheter features a molded proximal end bifurcate with two distinct luminal passages. The inflation lumen terminates into a distally mounted balloon made of polyamide. The balloon is designed with a waist formed into the middle of the balloon to allow accurate balloon placement. Upon reaching a specified pressure, the waist will expand to the rated balloon diameter and dilate the valve to the rated diameter. The distal lumen terminates at the tip of the catheter and will accept the passage of the 0.035" guidewire. This lumen has 3 radiopaque platinum marker bands. One under each of the balloon shoulders and one located at the "waist" or center of the balloon for placement using fluoroscopy. The catheter is white in color and the balloon material is clear. The catheter is packaged in a polyethylene sheath and is double packed in two heat sealed Tyvek pouches.

Biocompatibility Testing: The materials used in the NuMED NuCLEUS-X PTV Catheter are the same as those used in the already approved Z-MED-X PTV Catheter (510(k) #K022722) which were tested for biocompatibility in compliance with the Tripartite Biocompatibility Guidance for Medical Devices.

Test results indicate that all materials demonstrate the biocompatibility of the NuMED catheter and are on file at NuMED, Inc.

Laboratory (Bench) Testing: All bench testing was performed in accordance with GMP's and the results are kept on file at NuMED, Inc. Copies are included as an attachment.

Intended Use: This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.

- A patient with isolated pulmonary stenosis.
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.

Comparison Information:

MODEL:	NUMED Z-MED-X PTV CATHETER	NUMED NUCLEUS-X PTV CATHETER
Indications:	This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve. ▪ A patient with isolated pulmonary stenosis. ▪ A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.	This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve. ▪ A patient with isolated pulmonary stenosis. ▪ A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not require surgical intervention.
Shaft Size:	6-9Fr	9Fr
Guidewire Size:	0.035"	0.035"
Balloon Diameter:	8-10mm, 12mm, 14-16mm, 18mm, 20mm, 22mm, 25mm, 28mm, and 30mm	18mm, 20mm, 22mm, 25mm, 28mm, and 30mm.
Balloon Length:	2-6cm	4-6cm
Materials:	Shaft: Pebax Balloon: PES2 Image Band: Platinum	Shaft: Pebax Balloon: PES2 Image Band: Platinum
Construction:	Coaxial construction with distally mounted non-compliant balloons.	Coaxial construction with distally mounted non-compliant balloon.

RISK ANALYSIS

Attached is a copy of our FMECA showing our risk analysis of this product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 10 2008

NuMED, Inc.
c/o Ms. Nichelle LaFlesh
Regulatory Affairs Manager
2880 Main Street
Hopkinton, NY 12965

Re: K081680
Trade/Device Name: NuCLEUS-X
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (Two)
Product Code: DQY
Dated: June 16, 2008
Received: June 17, 2008

Dear Ms. LaFlesh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081680

Device Name: **NuCLEUS-X PTV Catheter**

Indications For Use:

This catheter is recommended for Percutaneous Transluminal Valvuloplasty (PTV) of the pulmonary valve.

- A patient with isolated pulmonary stenosis
- A patient with valvular pulmonary stenosis with other minor congenital heart disease that does not requrie surgical intervention.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K081680